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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------|------------------------------|----------------------|---------------------|------------------|
| 10/736,112 | 12/15/2003 | Jeffrey S. Ross | M2051-700410 5668 | |
| 37462 LANDO & AN | 7590 11/04/200 ASTASL LLP | 9 | EXAMINER | |
| ONE MAIN ST | REET, SUITE 1100 | | DAVIS, MINH TAM B | |
| CAMBRIDGE, MA 02142 | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 11/04/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ll-a.com gengelson@ll-a.com

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| Office Action Comments | 10/736,112 | ROSS, JEFFREY S. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | MINH-TAM DAVIS | 1642 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>22 Ju</u> | ily 2009 | | | | | |
| | action is non-final. | | | | | |
| ·= | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| ologica in absordance with the practice ander E | x parte gadyle, 1000 O.B. 11, 40 | 0.0.210. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1,8,10-16,33 and 34</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1,8,10-16, 33-34</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | r | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | , | | | | |
| | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) | 5) Notice of Informal P | atent Application | | | | |
| Paper No(s)/Mail Date 6) L Other: | | | | | | |

DETAILED ACTION

Claims 1, 8, 10-16, 33-34 are examined in the instant application.

Withdrawn Rejection

The following rejections have been withdrawn: 1) 112, second paragraph, in view of the amendment, and 2) 112, first paragraph, item 1, in view that Bostwick et al evaluate the immunohistochemical level of PSMA level subjectively, as compared to its semi-automated quantitative determination in the post filing reference by Perner et al.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, 10-16, 33-34 remain rejected under 35 U.S.C. 112, first paragraph, because it is not clear which of two PSMA variant sequences, SEQ ID NO:1 or SEQ ID NO:2, is detected by the claimed method, in view that variants of a sequence do not necessary express at the same level as that of the corresponding wild type, as taught by Schmid et al, and Conner et al, all of record.

Rejection remains because the response does not address this issue.

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Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS October 22, 2009

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643